

EU DECLARATION OF CONFORMITY

The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

and authorized representative:
PATIENT GUARD LTD
LANCASTER HOUSE,
AMY JOHNSON WAY,
BLACKPOOL, LANCASHIRE,
FY4 2RP, UNITED KINGDOM
INFO@PATIENTGUARD.CO.UK

declare under their sole responsibility, that the PPE described hereafter:

AlphaTec™ 16-650

Products manufactured as of: [2026/10/05]

PPE to be used against category III risks

EN388: 2016



X141B

EN 407



X2XXXXX2XXXX

EN 407



EN ISO 374-1:2016
Type B



KLT

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020, EN407:2020 , EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2026/0519, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VIII (Module D) of the Regulation under the supervision of the Notified Body:



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2026/10/05

EU DECLARATION OF CONFORMITY

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ANSELL HEALTHCARE EUROPE N.V.
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BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

declares under his sole responsibility, that the PPE described hereafter:

AlphaTec® 16-650

Products manufactured as of: [2024/12/05] and till: [2026/10/04]

PPE to be used against category III risks

EN388: 2016



X141B

EN 407



X2XXXX

EN ISO 374-1:2016
Type B



KLT

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020 , EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/0995.02, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VIII (Module D) of the Regulation under the supervision of the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2024/12/05

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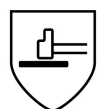
declares under his sole responsibility, that the PPE described hereafter:

AlphaTec® 16-650

Products manufactured as of: [2021/10/05] and till: [2024/12/04]

PPE to be used against category III risks

EN388: 2016



X141B

EN 407



X2XXXX

EN ISO 374-1:2016
Type B



KLT

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2021/0995, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2021/10/05

EU DECLARATION OF CONFORMITY

The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

declares under his sole responsibility, that the PPE described hereafter:

AlphaTec® 16-650

Products manufactured as of: [2019/01/03] and till: [2021/10/04]

PPE to be used against category III risks

EN 407



X2XXXX

**EN ISO 374-1:2016
Type B**



KLT

EN 388



X141B

EN ISO 374-5:2016



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 407:2004, EN ISO 374-1:2016 Type B, EN 388:2016, EN 420:2003 + A1:2009, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/0005, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2019/01/03

EU DECLARATION OF CONFORMITY

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BELGIUM
WWW.ANSELL.COM

declares under his sole responsibility, that the PPE described hereafter:

Gladiator™ 16-650

Products manufactured till: [2019/01/02]

PPE to be used against category III risks

EN 374



EN 374



EN 388



X241

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 374:2003, , EN 388:2003, EN 420:2003 + A1:2009 and is identical to the PPE which is subject to the EC Type examination; under certificate number 03209654 issued by the Notified Body:

**CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM**

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

**CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM**

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2009/12/14